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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,781	01/09/2001	Roopa Reddy	PC-0032 US	8475

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EXAMINER
RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
1642	6

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/757,781	REDDY ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *election facsimile cover sheet* .

DETAILED ACTION

1. Claims 1-22 are pending in the application and are currently subject to a restriction and election requirement.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1, 2 and 4-8, insofar as the claims are drawn to isolated nucleic acid molecule, or fragment or variant thereof, a vector comprising said nucleic acid molecule, a host cell comprising said vector, and a method for producing a polypeptide encoded by said nucleic acid molecule comprising culturing said host cell, wherein said nucleic acid molecule encodes a protein having the amino acid sequence set forth in SEQ ID NO: 1, classified in class 536, subclass 23.5, class 435, subclass 320.1, class 435, subclass 325, and class 435, subclass 70.1, respectively.

Group II. Claims 1 and 3-8, insofar as the claims are drawn to isolated nucleic acid molecule, a vector comprising said nucleic acid molecule, a host cell comprising said vector, and a method for producing a polypeptide encoded by said nucleic acid molecule comprising culturing said host cell, wherein said nucleic acid molecule encodes a protein having the amino acid sequence set forth in SEQ ID NO: 2, classified in class 536, subclass 23.5, class 435, subclass 320.1, class 435, subclass 325, and class 435, subclass 70.1, respectively.

Group III. Claims 9-12, insofar as the claims are drawn to a method for detecting the expression of a nucleic acid molecule, wherein method comprises hybridizing nucleic acids of a sample to a nucleic acid encoding

the amino acid sequence set forth in SEQ ID NO: 1 or the complement thereof, classified in class 435, subclass 6.

Group IV. Claims 9-12, insofar as the claims are drawn to a method for detecting the expression of a nucleic acid molecule, wherein method comprises hybridizing nucleic acids of a sample to a nucleic acid encoding the amino acid sequence set forth in SEQ ID NO: 2 or the complement thereof, classified in class 435, subclass 6.

Group V. Claims 13 and 14, insofar as the claims are drawn to a method for screening candidate compounds that bind a nucleic acid molecule, wherein said nucleic acid molecule encodes the amino acid sequence set forth in SEQ ID NO: 1, classified in class 435, subclass 4.

Group VI. Claims 13 and 14, insofar as the claims are drawn to a method for screening candidate compounds that bind a nucleic acid molecule, wherein said nucleic acid molecule encodes the amino acid sequence set forth in SEQ ID NO: 2, classified in class 435, subclass 4.

Group VII. Claims 15 and 16, insofar as the claims are drawn to a polypeptide or a portion thereof, wherein said polypeptide consists of the amino acid sequence set forth in SEQ ID NO: 1, classified in class 530, subclass 350.

Group VIII. Claims 15 and 16, insofar as the claims are drawn to a polypeptide or a portion thereof, wherein said polypeptide consists of the amino acid sequence set forth in SEQ ID NO: 2, classified in class 530, subclass 350.

Group IX. Claims 17 and 18, insofar as the claims are drawn to a method for screening candidate compounds that bind a polypeptide consisting of the

amino acid sequence set forth in SEQ ID NO: 1, classified in class 435, subclass 4.

Group X. Claims 17 and 18, insofar as the claims are drawn to a method for screening candidate compounds that bind a polypeptide consisting of the amino acid sequence set forth in SEQ ID NO: 2, classified in class 435, subclass 4.

Group XI. Claims 19 and 20, insofar as the claims are drawn to an antibody that binds specifically to a polypeptide consisting of the amino acid sequence set forth in SEQ ID NO: 1 and a method for producing said antibody, classified in class 530, subclass 387.1 and class 424, subclass 185.1, respectively.

Group XII. Claims 19 and 20, insofar as the claims are drawn to an antibody that binds specifically to a polypeptide consisting of the amino acid sequence set forth in SEQ ID NO: 2 and a method for producing said antibody, classified in class 530, subclass 387.1 and class 424, subclass 185.1, respectively.

Group XIII. Claims 21 and 22, insofar as the claims are drawn to a method for diagnosing, wherein said method comprises an immunoassay comprising an antibody that binds specifically to a polypeptide consisting of the amino acid sequence set forth in SEQ ID NO: 1, classified in class 435, subclass 7.1.

Group XIV. Claims 21 and 22, insofar as the claims are drawn to a method for diagnosis, wherein said method comprises an immunoassay comprising an antibody that binds specifically to a polypeptide consisting of the amino

acid sequence set forth in SEQ ID NO: 2, classified in class 435, subclass 7.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions in groups I, II, VII, VIII, XI, and XII are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods and therefore, the claimed products are distinct.

Inventions in groups I-VI and IX-XIV are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success and therefore, the claimed methods are distinct.

Inventions in groups I and II and groups III and IV, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the nucleic acid molecule can be used in a materially different process of using that product, such as producing a polypeptide encoded by said nucleic acid molecule.

Inventions in groups I and II and groups V and VI, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the nucleic acid molecule can be used in a materially different process of using that product, such as producing a polypeptide encoded by said nucleic acid molecule.

Inventions in groups VII and VIII and groups XI and XII, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can

be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the polypeptide can be used in a materially different process of using that product, such as using said polypeptide as an immunogen to produce an antibody that binds said polypeptide.

Inventions in groups VII and VIII and groups IX and X, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the polypeptide can be used in a materially different process of using that product, such as using said polypeptide in an assay to screen candidate molecules to identify a molecule that binds said polypeptide.

Inventions in groups XI and XII and groups XIII and XIV, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the antibody can be used in a materially different process of using that product, such as isolating the polypeptide to which the antibody binds by affinity chromatography.

The inventions in groups I and II and groups VII-XIV are not at all related because the products of groups I and II are not specifically used in any of the steps of the claimed methods in groups VII-XIV.

The inventions in groups VII and VIII and groups I-VI, XIII, and XIV are not at all related because the products of groups VII and VIII are not specifically used in any of the steps of the claimed methods in groups I-VI, XIII, and XIV.

The inventions in groups XI and XII and groups I-VI and IX-XII are not at all related because the products of groups XI and XII are not specifically used in any of the steps of the claimed methods in groups I-VI and IX-XII.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. The groups of inventions set forth above are generic to a plurality of disclosed patentably distinct inventions and therefore further subject to a restriction between species of invention.

Claim 4 is generic to a plurality of disclosed patentably distinct species comprising (a) a nucleic acid sequence of SEQ ID NO: 3 or the complement thereof, (b) a fragment of SEQ ID NO: 3 or the complement thereof, and (c) a variant of SEQ ID NO: 3 or the complement thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, i.e., one of (a)-(c), even though this requirement is traversed.

Claim 4 is further generic to a plurality of disclosed patentably distinct species comprising fragments of SEQ ID NO: 3, or the complement thereof, wherein said fragment is selected from the group consisting of SEQ ID NO: 4-11. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, i.e., one of SEQ ID NO: 4-11, even though this requirement is traversed.

Alternatively, claim 4 is further generic to a plurality of disclosed patentably distinct species comprising variants of SEQ ID NO: 3 selected from the group consisting of SEQ ID NO: 12-19. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, i.e., one of SEQ ID NO: 12-19, even though this requirement is traversed.

Alternatively, claim 4 is generic to a plurality of disclosed patentably distinct species comprising (a) a nucleic acid sequence of SEQ ID NO: 20 or the complement thereof, (b) a fragment of SEQ ID NO: 20 or the complement thereof, and (c) a variant of SEQ ID NO: 20 or the complement thereof. Applicant is required under 35

U.S.C. 121 to elect a single disclosed species, i.e., one of (a)-(c), even though this requirement is traversed.

Claim 4 is further generic to a plurality of disclosed patentably distinct species comprising fragments of SEQ ID NO: 20, or the complement thereof, wherein said fragment is selected from the group consisting of SEQ ID NO: 21-39. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, i.e., one of SEQ ID NO: 21-39, even though this requirement is traversed.

Alternatively, claim 4 is further generic to a plurality of disclosed patentably distinct species comprising variants of SEQ ID NO: 20 selected from the group consisting of SEQ ID NO: 12-19. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, i.e., one of SEQ ID NO: 40-56, even though this requirement is traversed.

Claim 13 is generic to a plurality of disclosed patentably distinct species comprising methods in which said molecules or compounds are selected from the group consisting of (a) DNA molecules or RNA molecules, (b) peptide nucleic acids, (c) artificial chromosome constructions, (d) peptides, (e) transcription factors, (f) repressors, and (g) regulatory molecules. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, i.e., one of (a)-(g), even though this requirement is traversed.

Claims 15 and 16 are generic to a plurality of disclosed patentably distinct species comprising (a) an amino acid sequence of SEQ ID NO: 1, (b) an antigenic epitope of SEQ ID NO: 1, and (c) a biologically active portion of SEQ ID NO: 1. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, i.e., one of (a)-(c), even though this requirement is traversed.

Alternatively, claim 15 is generic to a plurality of disclosed patentably distinct species comprising (a) an amino acid sequence of SEQ ID NO: 1, (b) an antigenic epitope of SEQ ID NO: 1, and (c) a biologically active portion of SEQ ID NO: 1. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, i.e., one of (a)-(c), even though this requirement is traversed.

Claim 17 is generic to a plurality of disclosed patentably distinct species comprising methods in which said molecules or compounds are selected from the group consisting of (a) DNA molecules or RNA molecules, (b) peptide nucleic acids, (c) peptides or proteins, (d) mimetics, (e) agonists, (f) antagonists, (g) antibodies or immunoglobulins, (h) inhibitors, and (i) drugs. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, i.e., one of (a)-(i), even though this requirement is traversed.

Note: Applicants are advised that a reply to this requirement must include an identification of a single species of the invention that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

6. Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
May 21, 2002

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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